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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,896	01/29/2004	Toru Matsumoto	8070-1004	2607

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,896	MATSUMOTO, TORU	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 9-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art on pages 1-3 and in Figure 1 of the instant application in view of Voo et al.

Applicant admits on pages 1-3 of the instant specification that an electrochemical sensor such as that depicted in Figure 1 of the instant application is known. Such an electrochemical sensor comprises a substrate 6 on which is formed an electrode 10. Layered on top of the electrode 10 are a binding layer 7, an enzyme layer 8 and a permeation-limiting layer 9. The permeation-limiting layer 9 can contain fluorine, as disclosed in JP Publication no. 2000-74870, which serves to prevent the adhesion of contaminants such as proteins and urea to the sensor. Therefore, the sensor comprises multiple organic material layers in addition to the enzyme layer,

which are responsible for various functions to improve the performance and reliability of the sensor. Applicant admits that it is conventional to store such an electrochemical sensor in a storage solution and to calibrate such a sensor with a calibration solution. However, problems with the sensors have been encountered when used in conjunction with such storage or calibration solutions. These problems include the growth of a mold or microorganisms in the solutions that cause an inactivation of the enzyme in the sensor and a detachment of the film constituting the sensor, leading to deterioration of sensor function and pH reduction of the storage solution. Applicant admits that in order to solve this problem, some of the prior art has used antibacterial and antiseptic materials such as sodium azide to prevent the growth of microorganisms. However, this type of material oxidatively decomposes and damages the enzyme used in the sensor. Therefore, it is desirable to solve this problem with the storage and calibration of electrochemical sensors in some other way. Applicant fails to teach that it is known in the art to incorporate a heterocycle having nitrogen and sulfur heteroatoms into the organic layers of an electrochemical sensor.

Voo et al teach of a composition or solution that can be used to calibrate electrochemical sensors, which detect analytes in biological fluids such as blood, serum, plasma or urine. The composition comprises a compound containing a heterocycle having nitrogen and sulfur heteroatoms. In particular, the composition comprises the preservatives 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one. 5-chloro-2-methyl-4-isothiazolin-3-one contains both oxo and a halogen directly bound to the heterocycle, and 2-methyl-4-isothiazolin-3-one contains oxo directly bound to the heterocycle. See lines 60-67 in column 1 and lines 1-4 in column 2 of Voo et al. Voo et al teach that electrochemical sensors are subject to

decomposition caused by microbes present in the solutions to which the sensor comes into contact such as a calibration solution. The microbes cause detrimental effects because of the acidic products formed. These acidic products serve to change the pH in the vicinity of the sensor, thus affecting the performance of the electrodes in the sensor. See lines 56-67 in column 2 and line 1 in column 3 of Voo et al. The composition taught by Voo et al serves to prevent the growth of microbes in the vicinity of electrochemical sensors so as to avoid the detrimental effects to the performance of the electrodes in the sensors caused by an acidic pH produced by the microbes.

Based upon the combination of Applicant's admitted prior art in the instant application and Voo et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to inhibit the growth of microorganisms in an electrochemical sensor subjected to a storage solution or a calibration solution by incorporating into the organic layers of the sensor a compound containing a heterocycle having nitrogen and sulfur heteroatoms, such as the composition taught by Voo et al, since Voo et al disclose that such a composition serves to prevent the growth of microbes in the vicinity of electrochemical sensors so as to avoid the detrimental effects to the performance of the sensors caused by the microbes without oxidatively decomposing or damaging the enzymes in the sensors.

5. Applicant's arguments filed December 28, 2005 have been fully considered but they are not persuasive.

The previous objections to the abstract and disclosure in the last Office action mailed on September 30, 2005 have been withdrawn in view of Applicant's amendments to the abstract and specification. The previous rejections of the claims under 35 USC 102(b) and 35 USC 102(e) as

being anticipated by Voo et al and Shin et al are withdrawn in view of the cancellation of claims 1-8.

Applicant argues that rejection of the claims under 35 USC 103 as being obvious over Applicant's admitted prior art on pages 1-3 and in Figure 1 of the specification in view of Voo et al by stating that the sensor of amended claim 9 is different from the sensor taught by Voo et al since it contains fluorine in the permeation limiting layer. The fluorine is introduced in order to prevent the adhesion of substances to the sensor. Therefore, Applicant argues that it would not be obvious to one of ordinary skill in the art to introduce an adhesive material containing a heterocycle to the surface of the permeation layer including fluorine since the fluorine teaches away from anything adhering to the sensor. In response to this argument, it is noted that it is known to include fluorine in the permeation-limiting layer of an electrochemical sensor for the purpose of preventing contaminants such as proteins and urea from adhering to the sensor. See JP Publication no. 2000-74870. It is also known to use antibacterial and antiseptic materials such as sodium azide to prevent the growth of microorganisms in and around electrochemical sensors. See page 3 of Applicant's specification. The addition of an antimicrobial substance, such as the ones including a heterocycle taught by Voo et al, to the known electrochemical sensor having fluorine in its permeation limiting layer would not go against the purpose of the fluorine to prevent the adhesion of protein and urea contaminants since this function would still be performed. The incorporation of the antimicrobial substances taught by Voo et al would instead, prevent the growth of microbes in and around the sensor without oxidatively decomposing or damaging the enzyme in the sensor, so as to prevent the inactivation of the enzyme and the detachment of the film constituting the sensor from the substrate, which are both

caused by the growth of microbes in and around an electrochemical sensor. The presence of fluorine in the permeation-limiting layer does not prevent one from placing an adhesive material containing an antimicrobial therein on the layer. Rather, it only prevents contaminants such as proteins and urea from becoming attached to the sensor. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to inhibit the growth of microorganisms in an electrochemical sensor subjected to a storage solution or a calibration solution by incorporating into the organic layers of the sensor a compound containing a heterocycle having nitrogen and sulfur heteroatoms, such as the composition taught by Voo et al, since Voo et al disclose that such a composition serves to prevent the growth of microbes in the vicinity of electrochemical sensors so as to avoid the detrimental effects to the performance of the sensors caused by the microbes without oxidatively decomposing or damaging the enzymes in the sensors.

Applicant also argues that the prior art does not disclose or mention that the compound containing a heterocycle having nitrogen and sulfur heteroatoms can prevent the detachment or cracks of a layer in an electrochemical sensor as disclosed in the instant invention. In response to this argument, it is noted that such a limitation is not positively claimed and merely constitutes an intended use of the heterocycle that is different than the intended use of the heterocycle taught by Voo et al, which is for the prevention of the growth of microbes in and around a sensor. The purpose for including a certain component in a device or composition in a prior art reference does not have to be the same as Applicant's purpose in order to render the addition of the component to a known prior art device or composition obvious. Such an intended use for preventing the detachment or cracks of a layer in an electrochemical sensor would inherently be

realized in the prior art electrochemical sensor having the antimicrobial taught by Voo et al added thereto.

For all of the above reasons, Applicant's arguments are not persuasive.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

February 22, 2006

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted]1700